1653

Dkt. 50634-B/JPW/SHS/AI

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Eric Rose, et al.

U.S. Serial No.: 09/053,872 Examiner: J. Russel

Filed : April 1, 1998 Group Art Unit: 1653

For : METHODS FOR INHIBITING THROMBOSIS IN A PATIENT WHOSE BLOOD IS SUBJECTED TO EXTRACORPOREAL CIRCULATION

#8
10/4/01

1185 Avenue of the Americas
New York, New York 10036
September 24, 2001

Assistant Commissioner for Patents
Washington, D.C. 20231

SIR:

COMMUNICATION IN RESPONSE TO MARCH 23, 2001 OFFICE ACTION AND PETITION FOR A FIVE-MONTH EXTENSION

This Communication is submitted in response to a March 23, 2001 Office Action issued by the United States Patent and Trademark Office in connection with the above-identified application. A Response to the March 23, 2001 Office Action was originally due April 23, 2001. Applicants hereby petition for a five month extension of time. Applicants have previously established small entity status. The required fee for a five month extension of time for a small entity is $925.00 and applicants enclose a check to cover this fee. Therefore, a response was due September 23, 2001. Since September 23, 2001 was a Sunday, under 37 C.F.R. §1.7, a response filed on the next succeeding day which is not Saturday, Sunday or a Federal Holiday, i.e. Monday September 24, 2001. Accordingly, this Communication is being timely filed.

Restriction Requirement Under 35 U.S.C. §121

The Examiner required restriction to one of the following allegedly distinct inventions under 35 U.S.C. §121:

I. Claims 23-32, allegedly drawn to an assay to determine the anticoagulant activity of a Factor IXa compound, classified in class 435, subclass 13;

II. Claims 33-37 and 52-57, allegedly drawn to a method of inhibiting thrombosis or clot formation, classified in class 424, subclass 145.1, and class 514, subclasses 2 and 44; and

III. Claims 38-51, allegedly drawn to a pharmaceutical compositions comprising Factor IXa compounds, classified in class 424, subclass 145.1, and class 514, subclasses 2 and 44.

The Examiner stated that the inventions are distinct, each from the other because of the following reasons: The Examiner stated that inventions III and I are related as product and process of use. The Examiner stated that the inventions can be shown to be distinct if either or both of the following can be shown:(1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). The Examiner stated that in the instant case, the product as claimed can be used in a materially different method of using that product, such as the invention of

Group II. The Examiner stated that inventions III and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). The Examiner stated that in the instant case, the product as claimed can be used in a materially different method of using that product, such as the invention or Group I. The Examiner stated that the inventions of Groups I and II and patentably distinct from each other because of the materially different method steps and the materially different results of each method. The Examiner stated that the invention of Group I is an in vitro method whose result is a numerical value characteristic of a Factor IXa compound. The Examiner stated that the invention of Group II is an in vivo method whose result is pharmaceutical treatment of a patient. The Examiner stated that because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. The Examiner stated that because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper. The Examiner stated that because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II or III, restriction for examination purposes as indicated is proper.

In addition, the Examiner has required that one of the allegedly patentably distinct species of Factor IXa compounds be elected from those which are set forth in claims 37, 41-44 and 46-51.

In response to this restriction requirement, applicant's undersigned attorney, on behalf of applicant, hereby elects, with traverse, to prosecute the invention of Examiner's Group III, i.e. claims 38-51, allegedly drawn to a pharmaceutical compositions comprising Factor IXa compounds.

Applicant notes that 35 U.S.C. §121 states, in part, that "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." [Emphasis added]. Applicant requests that the restriction of Examiner's Group III from Examiner's Groups I and II be withdrawn in view of the fact that the claims of Examiner's Group III are not independent of Examiner's Group's I and II. Applicant maintains that the claims of Examiner's Group III and Examiner's Groups I and II do not define patentably distinct inventions.

Under M.P.E.P. §802.1, "independent" means "there is no disclosed relationship between the subjects disclosed, that is, they are unconnected in design, operation, and effect." The claims of Examiner's Group I allegedly drawn to pharmaceutical compositions comprising Factor IXa compounds are related to the claims of Examiner's Groups II and III in that the claims in all groups are directly related to factor IXa.

The claims of Group I, allegedly drawn to an assay to determine the anticoagulant activity of a IXa compound are related to the claims of Examiner's Group II, which are allegedly drawn to a method of inhibiting thrombosis or clot formation involving Factor IXa because of the reliance of all identified claims in Group I and II on Factor IXa compounds as part of their design, operation, and effect. The claims of Examiner's Group III, allegedly drawn to pharmaceutical compositions comprising Factor IXa compounds are related to the claims of Examiner's Group II since the pharmaceutical compounds are derived from Factor IXa. Therefore, the claims of Examiner's Groups II and III are related. Accordingly, Examiner's Group I is related to Group III through their respective relation to the claims of Group II.

Applicant therefore respectfully asserts that two or more independent and distinct inventions have not been claimed in the subject application because the groups are not independent under M.P.E.P. §802.01. Therefore, restriction is improper under 35 U.S.C. §121.

Additionally, applicant points out that under M.P.E.P. §803, the Examiner must examine the application on the merits, even though it includes claims to distinct inventions, if the search and examination of an application can be made without serious burden. There are two criteria for a proper requirement for restriction, namely (1) the invention must be independent and distinct; AND (2) there must be a serious burden on the Examiner if restriction is not required.

Applicant maintains that there would not be a serious burden on the Examiner if restriction were not required. A search of prior art with regard to Group I, Claims 23-32 allegedly drawn to an assay to determine the anticoagulant activity of a Factor IXa compound will reveal whether any prior art exists as to a method of inhibiting thrombosis or clot formation(Group II) and pharmaceutical compositions comprising Factor IXa compounds (Group III). Since there is no burden on the Examiner to examine Groups I-III in the subject application, the Examiner must examine the entire application on the merits.

Applicant maintains that claims 23-57 define a single inventive concept. Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw the restriction requirement and examine claims 23-57 on the merits.

In addition, in response to this restriction requirement, applicant's undersigned attorney, on behalf of applicant, hereby elects, with traverse, the following species of Factor IXa: Glu-Gly-Arg chloromethyl ketone-inactivated human Factor IXa.

In addition, applicants request that upon the allowance of a generic claim, consideration of claims to additional species which are written in dependent form be considered.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone either of them at the number provided below.

No fee, other than the enclosed $925.00 fee for a five month extension of time, is deemed necessary in connection with the filing of this Communication. However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

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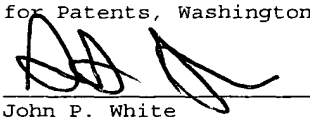
I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.



9-24-01

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